

Appl. No. 10/670,168
Amdt. dated November 22, 2011
Reply to Final Office Action of August 23, 2011

Amendments to the Drawings

A new drawing sheet includes new Figure 7.

Attachment: New Drawing Sheet

REMARKS

Applicants have received and carefully reviewed the Final Office Action mailed August 23, 2011. Currently, claims 1, 4, 5, 8, 28-30, 32, and 33 have been rejected. Claims 1, 28, and 30 have been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. A new drawing, FIG. 7, has been added in response to the objection to the drawings as not showing the main guidewire port and branch guidewire port being located at different locations. The new drawing is based on original FIG. 4 with the only alteration being that the two guidewire ports 39 and 41 are located apart from one another along the length of the system, as recited in paragraph 34 of the specification (as published in US 2004/0153136). The new drawing is thus fully described in the original specification. The specification has also been amended to include a description of FIG. 7. No new matter has been added. Favorable consideration of the following remarks is respectfully requested.

Objections to the Drawings

The drawings are objected to as failing to show the main and branch guidewire ports being located at different locations. New FIG. 7 has been added to show this claimed feature. This drawing is described in the original description in, for example, paragraph 34 of the publication, and is thus fully described and supported by the original disclosure. The features of the claims are thus shown in the drawings. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 1, 4, 5, 8, 28-30, and 32-40 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that the specification contains no disclosure of what constitutes the intermediate region or its length, thus there is no way for one of skill in the art to know what delineates the intermediate region or how to measure it. Applicants respectfully disagree. Claim 1 recites, “wherein the intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon.” Emphasis added. This claim language is fully supported by the original disclosure at, for example, paragraph 33 of the published application. The Office Action asserts

the specification defines the length of the *shaft* from the bond to the balloon as 1-100 cm, noting the length of the shaft from the bond to the balloon not only includes the intermediate region but also the proximal region and possibly the distal region. Applicants respectfully disagree. The Office Action appears to be interpreting this length to be the entire length of the shaft 26.

Applicants submit this is an incorrect interpretation. The specification is describing the length of distal shaft 26 and inflation tube 22 between the bond and the balloon, but not the entire length of the shaft 26 and tube 22. This is clear based on the fact that the specification is describing this length with regard to both the shaft 26 and inflation tube 22. The specification states "Bond portion 24 is attached to inflation tube 22 at a point distal to the proximal end of inflation tube 22." See paragraph 30. Applicants submit that one of ordinary skill in the art would understand from the specification that the distance of 1-100 cm between the bond and the balloon is not intended to necessarily include the entire shaft 26 or tube 22, but instead refers to just the portion of the tubes between the bond and balloon.

Additionally, as clearly shown in FIG. 4, the shaft 26 extends along the balloon and through the bond. As the claim clearly states the intermediate portion is between the bond and balloon, the entire length of the shaft includes portions extending beyond this distance at the proximal and distal ends. Thus a shaft length between the bond and the balloon being 1-100 cm allows for the claimed intermediate region being 10-100 cm, indicating the intermediate region makes up the portion of the shaft 26 between the bond and balloon, as recited in the claims. Applicants submit that one of ordinary skill in the art could easily understand the intermediate region is the region between the bond and the balloon, as recited in the claims.

Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts the specification discloses the branch guidewire exit port being 50 to 150 cm from the distal end, but only with respect to an embodiment where the enclosure extends to the proximal end of the catheter. Applicants respectfully disagree. Applicants do not understand where the asserted teaching of the branch guidewire exit port being 50 to 150 cm from the distal end only in an embodiment with the branch enclosure extending to the proximal end of the catheter. Original claims 1 and 8 provide support for claim 8 as now presented. If this rejection is maintained, Applicants respectfully request the Office Action indicate where the asserted teaching is found that restricts the claimed embodiment to one in which the enclosure extends to the proximal end of the catheter.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 1, 4, 5, 8, and 30 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 1 has been amended to remove “at least.” Claim 30 has been amended to clarify the bond is spaced from the balloon by a distance suitable for use with first and second guidewires of less than 50 cm. The claims as amended are fully supported by the original specification, claims, and drawings. One of ordinary skill in the art would clearly understand that when a guidewire of less than 50 cm is used, the distance between the bond (guidewire port) and the balloon must be toward the smaller end of the 10-100 cm range. Reconsideration and withdrawal of the rejections are respectfully requested.

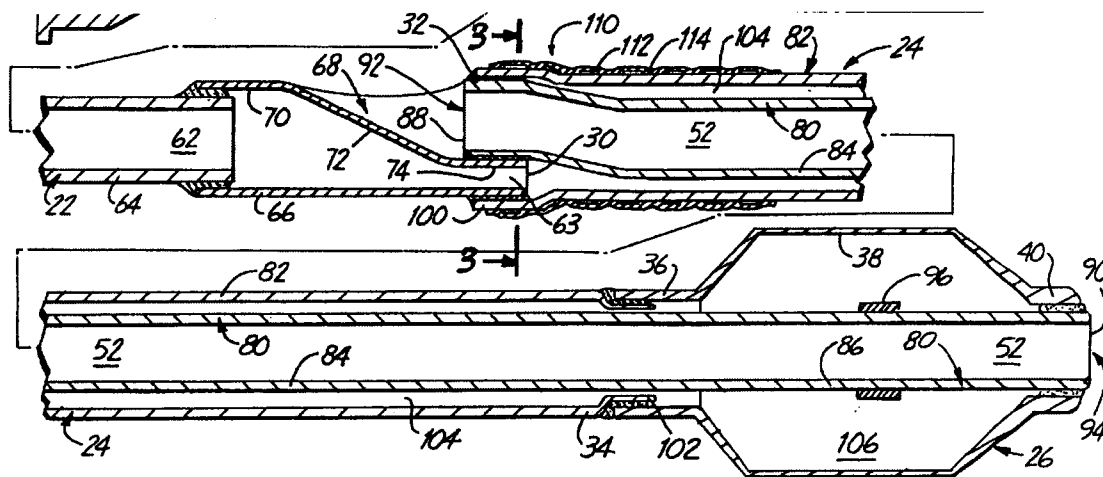
Claim Rejections – 35 U.S.C. § 103

Claims 1, 4, 5, 8, 28-30, and 32-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Keith et al. (U.S. Patent No. 6,273,879) in view of Adams et al. (U.S. Patent No. 6,099,497) and further in view of Sirhan (U.S. Patent No. 5,743,875). After careful review, Applicants respectfully traverse this rejection.

Nothing in the cited portions of Keith et al., Adams et al., or Sirhan et al. appears to disclose the features recited in independent claims 1 or 28. In paragraph 19 of the Response to Arguments section, the Office Action asserts that there is nothing that precludes the examiner from calling the combination of 22/66/24 in Keith the tubular member or that requires the balloon be directly in contact with the distal end of the tubular member. The claims have been amended to clarify a single piece, unitary tubular member with the balloon coupled directly to the various tubular members. As such, the three part combination of 22/66/24 of Keith cannot be seen to teach the claimed structure.

Keith teaches, “the main shaft section 22 thus has a longitudinally extending inflation lumen 62 extending therethrough from its proximal end 28 to its distal end 30.” As can be seen in FIG. 2 reproduced below, the distal end 30 of main shaft section 22 ends proximal to balloon 26. Instead of the proximal waist 36 of the balloon being coupled to the first tubular member 22, as asserted in the Office Action, Keith appears to teach proximal waist 36 coupled to the outer sleeve 82 of the intermediate sleeve 24. Neither Adams et al. nor Sirhan et al. appear to teach

what Keith lacks, thus even if one were to combine the references, one would not arrive at the system as claimed.



The Office Action acknowledges that Keith does not disclose a branch guidewire enclosure or a stent, and asserts that it would have been obvious to incorporate the two guidewire system and stent of Adams so the system of Keith would be capable of delivering a stent to an ostium or bifurcation. Regarding the claim limitation of “wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure,” the Office Action asserts that “proximal end region” has no defined limits and therefore the portion where the branch guidewire enclosure is bonded to the tubular member is considered the proximal end region, pointing to FIG. 17 showing the entire enclosure is not bonded. Applicants respectfully disagree. The Office Action appears to be asserting that because Adams shows embodiments (FIGS. 17, 18) in which a guidewire enclosure is not bonded along the entire enclosure, the reference inherently teaches the claimed limitation of a branch guidewire enclosure that is only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure. The Office Action appears to be asserting that because Adams doesn’t teach the opposite of the claimed structure (bonded along the entire length), it must teach the claimed structure (bonded only at a bond). Applicants respectfully disagree.

If the Examiner is considering the specific structure recited in the claims to be inherent in Adams, Applicants submit that there is no basis for such an interpretation. MPEP § 2112(IV) states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Applicants submit that the claimed structure, in particular the structure of the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure, is not necessarily present in Adams. It appears the Examiner is asserting that the structure of Adams could be modified to achieve the claimed structure, which is not a proper basis for rejection.

While Adams appears to teach a second guidewire lumen 136 disposed adjacent the first guidewire lumen 134, the reference does not appear to teach any specific type or location of bonding between the two lumens. Adams thus cannot be seen to provide any teaching or motivation for modifying Keith to have a branch guidewire enclosure bonded only to the first tubular member and only bonded at a bond at the proximal end region of the branch guidewire enclosure, as recited in the claim. Further, in the absence of any teaching or suggestion in the references, the Office Action has not provided any rational reason as to why one of ordinary skill in the art would have been motivated to modify Keith to include such a bonding structure.

The Office Action acknowledges that modified Keith does not disclose an intermediate region of 10-100 cm between the balloon and the bond, but asserts that Adams teaches the length of the branch enclosure which typically defines the distal tip in the intermediate region of the balloon could be made longer such that the distal tip resides in the branch vessel. This argument

is not understood because extending the length of the branch enclosure to extend distally beyond the intermediate region of the balloon such that the tip resides in the branch vessel would appear to lengthen the distal portion of the branch enclosure beyond the balloon. A careful reading of the claims shows the 10-100 cm intermediate region is specifically recited as being “between the bond and the balloon.” Thus extending the branch enclosure beyond the balloon would not affect the intermediate region. Adams does not appear to teach or suggest the 10-100 cm distance between the bond and the balloon, as claimed.

The Office Action asserts that because Sirhan discloses a balloon catheter having a guidewire exit port located at between 5 cm and 45 cm from the distal end of the catheter, it would have been obvious to modify the distance of the guidewire port and thus the intermediate portion of the branch guidewire portion in order to suit the particular intended use. Applicants respectfully disagree. Again, Applicants note the claim language clearly defines “the intermediate region of the branch guidewire enclosure is 10 cm to 100 cm in length between the bond and the balloon.” At best, Sirhan provides a total length from the exit port to the distal end of the catheter. Sirhan does not, however, provide any teaching or suggestion of a length between a bond and the balloon.

Further, Applicants submit that “in order to suit the particular intended use” does not provide the necessary rational reason required for obviousness. It appears the Office Action is asserting that one could modify the location of a guidewire port if one wanted to.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 Decision. The Office Action has not provided any articulated reasoning with rational underpinning to support the conclusion of obviousness. The Office Action appears to be asserting that one could modify Keith, Adams, and Sirhan to achieve the claimed structure, which is clearly an improper ground for obviousness. The Court in KSR further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 Decision. The Office Action has not provided any objective reason to modify Keith, Adams, and Sirhan in the manner recited in claim 1, other than relying on the instant specification, which is clear error.

Additionally, Applicants submit that even though Sirhan teaches a single, main guidewire exit port located 5-45 cm from the distal end of the catheter, this does not provide any motivation for modifying Keith and Adams to achieve an "intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon" as recited in the claim. Further, there is nothing in Keith, Adams, and Sirhan that teaches or suggests the combination of "wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure" and "wherein the intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon." The Office Action has not provided any teaching or suggestion of the claimed structure. Further there is no rational reason for one of ordinary skill in the art to modify the references to achieve the claimed structure. The Office Action asserts the motivation for modifying Keith to achieve the claimed structure is to modify a dimension to suit the intended use of the device for example size of the patient or location of the body being treated. Applicants submit this "motivation" appears to be based on the present specification, which is improper. Alternatively, the motivation appears to be one of modify Keith merely because on "could," which is improper. See KSR quote above.

For at least these reasons, claim 1 is believed to be patentable over Keith et al. in view of Adams et al. and Sirhan et al. For similar reasons and others, claims 4, 5, 8, 39, and 40 which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Keith et al. in view of Adams et al.

Regarding independent claim 28 the Office Action asserts that Adams and Sirhan teach modifying dimensions, thus it would be well within the level of one of ordinary skill in the art to modify the distance of the bond to meet the limitations of the claim. Applicants respectfully disagree. As discussed above, Adams does not appear to provide any teaching regarding how and where the first and second guidewire lumens are bonded. Further, Adams does not appear to teach or suggest any dimensions for the secondary guidewire lumen between any possible bonding region and the balloon. Also as discussed above, while Sirhan appears to provide dimensions for the location of a primary guidewire port, this does not provide any suggestion or

motivation for one of ordinary skill in the art to modify the length of a branch guidewire enclosure distal of a single bond region.

Additionally the asserted motivation of modifying dimensions "to suit the intended use of the device" does not provide the rational reason required for obviousness. The Office Action appears to be asserting that it would have been obvious to modify Keith, if one wanted to do so. Applicants submit this is not a proper basis for obviousness. For at least these reasons, claims 28-30 and 32-38 are believed to be patentable over Keith et al. in view of Adams et al. and Sirhan et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gil M. Vardi et al.

By their Attorney,

Date: November 22, 2011

/j. scot wickhem/
J. Scot Wickhem, Reg. No. 41,376
SEAGER, TUFTE, & WICKHEM, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

Attachment: New Drawing Sheet